



UNITED STATES PATENT AND TRADEMARK OFFICE

HL

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,827	02/10/2004	Kathryn B. Horwitz	2848-39-2	3737
22442	7590	10/15/2004		
SHERIDAN ROSS PC 1560 BROADWAY SUITE 1200 DENVER, CO 80202				
			EXAMINER	
			LI, RUIXIANG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/776,827

Applicant(s)

HORWITZ ET AL.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/08/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,8,10-25 and 84-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1,7,8,10-25 and 84-92 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>02/10/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicants' preliminary amendment filed on February 10, 2004 has been entered. Claims 2-6, 9, and 26-83 have been canceled. Claims 1, 7, 8, 10, 14, 15, and 21-25 have been amended. Claims 84-92 have been added. The Examiner overlooked the preliminary amendment filed on February 10, 2004 and issued a restriction requirement on July 2, 2004, which restricted claims 1-83 to eleven groups of inventions. In response to the restriction requirement, Applicants pointed out the fact that all claims except claims of group I had been canceled. In addition, Applicants elected, without traverse, Group I (original claims 1-25) on August 2, 2004. Thus, in view of Applicants' preliminary amendment and the restriction requirement, claims 1, 7, 8, 10-25, and 84-92 are pending and under consideration.

However, in response to item 8 of the restriction requirement, wherein the Examiner requires an election of a single gene from Tables 1-7, Applicants elected SEQ ID NO: 10 (KIAA0040 gene), with traverse, on August 2, 2004.

Beginning at the bottom of page 8 of Applicants' response filed on August 2, 2004, Applicants argue that the presentation of 10 genes in the claimed method of present divisional application is a result of the prosecution of the parent application (U.S. application Serial No. 09/814,915), where 10 genes were examined with regard to the method in the parent application. This is not found persuasive because the restriction requirement issued in the parent Application 09/814,915 set forth a species

election regarding the genes regulated by PR-A and/or PR-B, which are listed in Tables 1-7. In the instant case, the restriction requirement sets forth an additional invention group for each gene listed in the tables. Moreover, each individual gene represents a structural and functionally distinct entity that is capable of supporting a separate patent. The search and consideration of more than a single gene constitutes an undue search burden on the office, given the ever-increasing size of the database.

At the middle of page 9, Applicants, citing MPEP 803.02 regarding restriction practice with respect to Markush claims, argue that the restriction between genes used in the assay is not appropriate, even if the groups are independent and distinct, as the groups are linked by the common utility and structural feature, and because recitation by enumeration was the only reasonable way to claim this invention. This is not found to be persuasive because while the genes listed in claim 1 share a common utility, i.e., identifying an agonist of progesterone receptor, they do not have a substantial structure similarity. Thus, unity of invention does not exist among the genes listed in claim 1, according to *Harnisch* test for unity of invention. The Examiner's position is supported by the fact that the nucleic acid sequences of genes are different; searching the nucleic acid sequence of one gene does not reveal the nucleic acid sequence of another gene.

At the bottom of page 9, Applicants argue that given that there are 105 genes described for use in the claimed method, prosecuting each and every gene individually could create an undue burden on the Applicants and the patent Office.

This is not found to be persuasive because restriction to one of the following inventions is required under 35 U.S.C.121. Expense is not the criteria for practice of restriction requirement. It will be necessary to file multiple applications to cover all the genes if Applicants desire to do so. It is also noted that the search and examination of more than one gene constitutes an undue burden on the examiner.

At page 10, Applicants argue that the search and examination of the claims is not expected to be overly burdensome because the claims are not directed to the genes themselves, but rather to the use of the genes as endpoints in an assay for identification of progesterone receptor agonists. The Examiner can readily limit the search by cross-referencing the sequences against the progesterone receptor aspect of the invention. This is not found to be persuasive because no matter whether the claims are directed to the products (the genes) or to the use of the products (use of the genes for identification of progesterone receptor agonists), a thorough search and careful consideration is required for each gene whereas the search and consideration of more than one gene presents an undue burden on the Examiner.

Accordingly, the requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

2.The information disclosure statement filed on February 10, 2004 has been considered by the Examiner and a signed copy of form PTO-1449 is attached to the office action.

Claim Objections—Minor Informalities

3. Claims 1, 7, 8, 10-25, and 84-92 2 are objected to because because they recite unelected subject matter (nucleic acid sequences, see claim 1, part b). Appropriate correction is required.

Conclusion

4. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Brenda.Brumback@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is

Art Unit: 1646

more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A handwritten signature in cursive script, reading "Ruixiang Li".

Ruixiang Li, Ph.D.
Examiner
October 7, 2004